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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin G. Reese

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EXAMINER

SMITH, CAROLYN L

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1631

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09/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,665	Applicant(s) REESE ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,13,14,17,20,22,23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,15,16,18,19,21,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04102009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 6/19/09, are acknowledged. Amended claims 1, 6, 9, 24, and 25 are acknowledged. Claims 22-23 and 26 remain withdrawn from consideration due to being drawn to non-elected Groups. Claims 2, 3, 13, 14, 17, 20 remain withdrawn from consideration due to being drawn to non-elected species.

Applicant's arguments, filed 6/19/09, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The information disclosure statement, filed 4/10/09, has been considered by the Examiner.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are herein under examination.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Blumenfeld et al. (US 6,528,260 B1). This rejection is maintained and reiterated for reasons of record.

Blumenfeld et al. disclose a method for determining whether an individual has an enhanced probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first two paragraphs), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 84, second paragraph), comparing zygosity of markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 14, last paragraph; col. 31, 32, 33, and col. 83, second paragraph) as well as determining whether a marker score indicates high probability of exhibiting a phenotypic attribute (col. 84, second paragraph; col. 91, second paragraph) using software on a computer (col. 87, second paragraph; col. 97, second paragraph to col. 98, last paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose using promoter sequences (col. 10, last paragraph; col. 31, first paragraph; col. 64, fifth paragraph), as stated in instant claims 4 and 5. Blumenfeld disclose selecting markers prioritized by degree of phenotypic significance and markers that map at least about 1000 discrete loci (col. 39, last paragraph to col. 40, first paragraph; col. 79, third paragraph; col. 89,

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line 47 to col. 90, first paragraph), as stated in instant claim 7. Blumenfeld et al. disclose performing analysis when some information concerning the biology of the trait is available (col. 21, second paragraph) and selecting markers from some of the Tables (i.e. 11A-B; col. 12, third paragraph; col. 17, first three paragraphs; col. 25, second paragraph) which represents scoring matrix prioritizing markers with respect to criteria of quality of supporting research, as stated in instant claim 8. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col. 9, fourth paragraph), as stated in instant claims 9, 10, 15, 16, (and i.e. see Tables above,

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inherently prior to communication to individual, the identity of individual is not associated with data, as stated in instant claim 21). Blumenfeld et al. disclose studying physiological consequences at the cellular and organism level (col. 45, last paragraph to col. 46, first paragraph), various databases with information on sequence variations and how genotypes affect common diseases, drug responses, and other complex phenotypes (col. 111, first and third paragraphs), and user-specified thresholds of significance (col. 32, first paragraph) as stated in instant claims 11 and 12. Blumenfeld et al. disclose taking into account effects of subpopulations with discriminatory potential or considering close familial relationships (col. 110, second paragraph) which represents an organizational matrix that groups phenotypic characteristics related to similar physiological systems together, as stated in instant claim 18. Blumenfeld et al. disclose assessing risk to better target therapeutic strategies defining individual drug usage based on benefit/risk prognosis as well as efficacy/tolerance prognosis (col. 9, first paragraph) and scoring the results of determination of the identity of a nucleotide at a marker with respect to the test subject's risk of contracting disease, drug response, or chances of suffering side effects (col. 41, second paragraph) which represents ranking phenotypic characteristics as a function of potential impact on the individual's lifestyle, as stated in instant claim 19. Blumenfeld et al. disclose characteristics of genomic ethnicity of an individual (col. 64, last paragraph; col. 95, fifth paragraph). Blumenfeld et al. disclose diseases including disorders of male infertility (col. 27, first paragraph) and studies among affected relatives by analysis of two individuals, including sib pair analysis (col. 80, second paragraph). Blumenfeld et al. disclose population-based association studies (col. 83, last paragraph) and inclusion criteria for selection as well as linkage studies and statistical analysis (col. 83, second to last paragraph

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to col. 85, last paragraph), and pharmacogenomic analysis (col. 1, second paragraph), as stated in instant claims 24 and 25.

Thus, Blumenfeld et al. anticipate the instant invention.

Applicant summarizes Blumenfeld et al. and the instant invention. Applicant argues that Blumenfeld et al. disclose association studies in which a phenotype is linked to a single genotype and do not disclose a method of deriving a probability of a phenotypic characteristic based on an individual's genotype at a preselected set of markers, markers shown through association and other studies to be linked directly or indirectly to a certain phenotypic characteristic (i.e. a particular disease state), as stated in instant claim 1. This statement is found unpersuasive as instant claim 1 does not specifically disclose the above limitations as suggested by Applicant (i.e. deriving a probability, markers shown through association and other studies to be linked directly or indirectly). Applicant argues that Blumenfeld et al. do not disclose the limitations in instant claim 9. This statement is found unpersuasive as Blumenfeld et al. disclose a method for determining whether an individual has an enhanced probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first two paragraphs), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 84, second paragraph), comparing zygosity of markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 14, last paragraph; col. 31, 32, 33, and col. 83, second

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paragraph) as well as determining whether a marker score indicates high probability of exhibiting a phenotypic attribute (col. 84, second paragraph; col. 91, second paragraph) using software on a computer (col. 87, second paragraph; col. 97, second paragraph to col. 98, last paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col. 9, fourth paragraph), as stated in instant claim 9. Applicant's arguments are deemed unpersuasive for the reasons set forth above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

September 18, 2009

/Carolyn Smith/
Primary Examiner
AU 1631